REMARKS

The Office Action dated November 18, 2004 presents the examination of claims 15-30. Claims 29 and 30 are allowed. Claims 15-23 and 25-27 are amended. Claim 28 is canceled. No new matter is inserted into the application.

Interview

A telephonic interview was held with the Examiner on February 9, 2005. In the Interview Summary, the Examiner writes:

> Applicant's proposed amendments to the claims, faxed to the examiner for consideration, were discussed with regard to outstanding issues under 35 USC 112, 2nd paragraph, and 102. Suggested claim language to further clarify terms such as "mainly" and "reacted amount" were made by examiner.

During the interview, the Examiner made several suggested claim amendments in order to place the claims into condition for allowance. Applicants respectfully submit that the claims have been amended to fully address and overcome the rejections of record, as discussed during the interview. Further, claim 27 is amended to recite the specific peptides disclosed in the specification that were used to immunize the test mammals. Specifically, on page 40, last line to page 41, line 5 of the specification, it is disclosed that peptide 13 (i.e., amino acids

316-328 of SEQ ID NO:1) and peptide 15 (i.e., amino acids 331-345 of SEQ ID NO:1) were used for immunization.

Applicants respectfully submit that claims 15-27 and 29-30 are in condition for allowance. The Examiner is therefore respectfully requested to issue a Notice of Allowability indicating the patentability of these claims. However, if any outstanding matters persist, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, prior to the issuance of an Advisory Action.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 15-28 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Claim 28 is canceled thus rendering rejection thereof moot. Applicants respectfully traverse the rejection of the pending claims. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

The Examiner points out several alleged deficiencies in claims 15-26. The claims are amended as suggested by the Examiner both in the Office Action and during the interview. Thus, the instant rejection is overcome.

With regard to claims 17, 22, 25, and 26, the Examiner asserts that the term "mainly" is a relative term, which renders the claims

indefinite. The term "mainly" is amended to "primarily" which was approved by the Examiner during the interview.

With regard to claims 19, 20, and 23, the Examiner argues that the term "reacted amount" is unclear. The term "reacted amount" is amended to either "first antibody-bound amount" or "second antibody-bound amount" as suggested by the Examiner during the interview.

Applicants respectfully submit that the pending claims particularly point out and distinctly claim the subject matter which is the present invention, such that the requirements of 35 U.S.C. § 112, second paragraph are satisfied. Withdrawal of the instant rejection is therefore respectfully requested.

Rejections under 35 U.S.C. § 102

Stelter et al.

The Examiner rejects claims 23-28 under 35 U.S.C. § 102(b) for allegedly being anticipated by Stelter et al. (*Eur. J. Biochem.*, 236:457 (1996)). Claim 28 is canceled thus rendering the rejection thereof moot. Applicants respectfully traverse the rejection of claims 23-27. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner maintains his assertion that

Stelter et al. teaches a method for measuring high molecular weight soluble CD14 proteins as recited in claims 23-26. Applicants respectfully submit that Stelter et al. fails to anticipate claims 23-26 as currently amended.

Claim 23 is directed to a method for selectively measuring high molecular weight soluble CD14 proteins in a body fluid sample from a patient comprising both high and low molecular weight soluble CD14 proteins. The method of claim 23 utilizes an anti-CD14 antibody which selectively binds to an amino acid sequence of from positions 316 to 356 of SEQ ID NO: 1.

In contrast, the antibody used for Western blotting by Stelter et al. is an anti-CD14 polyclonal antibody, which would non-selectively bind to both high and low molecular weight soluble CD14 proteins. Therefore, it would be impossible to selectively measure either one of the high molecular weight soluble CD14 protein or the low molecular weight soluble CD14 protein using the polyclonal anti-CD14 antibody disclosed by Stelter et al. Thus, Stelter et al. fails to anticipate claims 23-26.

Further, Stelter et al. fails to disclose or suggest an isolated antibody prepared by immunizing a mammal with a peptide consisting of amino acids 316-328 or amino acids 331-345 of SEQ ID NO: 1, as recited in claim 27. Stelter et al. only describes an

anti-CD14 antibody against native CD14. There is no description of an antibody prepared by immunizing a mammal with a peptide consisting of amino acids 316-328 or amino acids 331-345 of SEQ ID NO: 1. As such, Stelter et al. fails to anticipate claim 27.

In conclusion, it is clear that Stelter et al. fails to anticipate the pending claims. Withdrawal of the instant rejection is therefore respectfully requested.

Landmann et al.

The Examiner rejects claims 23-28 under 35 U.S.C. § 102(b) for allegedly being anticipated by Landmann et al. (*J. Inf. Dis.* 171:639 (1995)). Claim 28 is canceled thus rendering the rejection thereof moot. Applicants respectfully traverse the rejection of claims 23-27. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

The Examiner asserts that Landmann et al. teaches a method for measuring high molecular weight soluble CD14 proteins as recited in claims 23-26. Applicants respectfully disagree.

Claim 23, as amended, is directed to a method for selectively measuring high molecular weight soluble CD14 proteins in a body fluid sample from a patient comprising both high and low molecular weight soluble CD14 proteins. The method utilizes an anti-CD14

antibody which selectively binds to an amino acid sequence of from positions 316 to 356 of SEQ ID NO: 1.

In contrast, the antibodies used in Western blotting in Landmann et al. are the 3C10 antibody and the anti-CD14 polyclonal antibody. As evidenced by WO 96/20957 (of record), the 3C10 antibody selectively binds to amino acid positions 7-14 of the CD14 amino acid sequence. Further, as discussed above, the anti-CD14 polyclonal antibody is non-specific and would therefore bind both a high molecular weight soluble CD14 protein and a low molecular weight soluble CD14 protein. Thus, given the antibodies utilized by Landmann et al., it would be impossible to selectively measure high molecular weight soluble CD14 proteins. Landmann et al. therefore fails to anticipate claims 23-26.

Further, Landmann et al. fails to disclose or suggest an isolated antibody prepared by immunizing a mammal with a peptide consisting of amino acids 316-328 or amino acids 331-345 of SEQ ID NO: 1, as recited in claim 27. As such, Landmann et al. fails to anticipate claim 27.

In conclusion, it is clear that Landmann et al. fails to anticipate the newly pending claims. Withdrawal of the instant rejection is therefore respectfully requested.

Rejection under 35 U.S.C. §§ 102/103

The Examiner rejects claims 27-28 under 35 U.S.C. § 102(b) for allegedly being anticipated by, or in the alternative under 35 U.S.C. § 103(a) for allegedly being obvious over, Leturcq '025 (WO 94/28025). Claim 28 is canceled thus rendering rejection thereof moot. Applicants respectfully traverse the rejection of claim 27. Reconsideration and withdrawal of the instant rejection are respectfully requested.

The Examiner asserts that the antibodies of Leturcq '025 are the same antibodies of the present invention, absent proof to the contrary. Applicants respectfully submit that the anti-CD14 antibody (antibody against a recombinant CD14) disclosed by Leturcq et al. is different from the antibody of the present invention.

Specifically, the present invention provides for an isolated antibody prepared by immunizing a mammal with a peptide consisting of amino acids 316-328 or amino acids 331-345 of SEQ ID NO:1. There is no description of such an antibody in Leturcq et al. Rather, Leturcq et al. discloses an antibody produced by immunization with a full-length sCD14 amino acid sequence. Thus, the antibody produced will be specific for those epitopes exposed on the surface of the CD14 protein. In contrast, the antibody recited in claim 27 only binds to an amino acid sequence wherein the

specific amino acid sequence (i.e., positions 316-328 or 331-345 of SEQ ID NO: 1) is present.

For these reasons, Laturcq et al. fails to anticipate or render obvious the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Conclusion

Applicants respectfully submit that the above remarks and/or amendments fully address and overcome the outstanding rejections and objections. For the foregoing reasons, Applicants respectfully request the Examiner to withdraw all of the outstanding rejections and objections, and to issue a Notice of Allowance indicating the patentability of claims 15-27 and 29-30. Early and favorable action of the merits of the present application is thereby respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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